Submitter Information

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Name of Device

Trade Name:	SCHILLER BP-200 plus
Common Name:	Automated Non-Invasive Blood Pressure Monitor System with Oxygen Saturation Measurement as an option
Classification Name:	System, measurement, blood pressure, non-invasive
Product Code:	DXN
Regulatory Class:	Class II (two)
Regulation Number:	21 CFR 870.1130

Legally-marketed predicate devices

Tango +, **K053209**, SunTech Medical Instruments Inc.

The SCHILLER BP-200 plus is substantially equivalent to the above mentioned device.

The following modules are used as an option:

- Oximeter: Masimo SET 2000 Oximeter **K990966**
- ECG Amplifier: SCHILLER Microvit MT-100 **K973735**
- QRS Trigger: SCHILLER ARGUS PB-1000 **K012226**

Description

The BP-200 plus, a microprocessor based non invasive blood pressure monitor and oxygen saturation measurement system intended to be used with stress-test systems, uses Korotkoff sounds to determine blood pressure and an optical ear sensor for oxygen saturation. An internal electric pump is used to inflate the cuff, and deflation is controlled by a valve. The BP-200 plus has the ability to make blood pressure at predetermined intervals (normally from a schedule determined by the physician), or on demand. Saturation measurements are updated once per second.
The BP-200 plus is powered by an external power supply (input: 230/110 V; output: 9V dc), and as an option by using four "AA" rechargeable batteries (≥ 2500 mAh). The batteries must be recharged with an external battery charger.

Intended Use

The BP-200 plus is intended to be used as an adjunct to exercise stress testing devices. It is intended to measure and display diastolic and systolic blood pressure, heart rate, percentage of oxygen saturation in arterial blood (SpO2) and pulse rate in adult or adolescent patients during stress tests. The BP-200 plus can be used for patients of both sexes and all races. The BP-200 plus should not be used with neonates.

Performance Data

Non-clinical tests:

The BP-200 plus has passed the tests according to the following standards:

- ANSI/AAMI SP10
- EN 60601-1
- EN 60601-1-2
- EN 60601-2-30
- EN 1060-1
- EN 1060-3
- ISO 9919

Clinical tests:

To verify the overall system efficiency the measurments of BP-200 plus are compared with manual auscultatory measurements as discribed in the ANSI/AAMI SP10 and the EN 60601-2-30. For the same reason the "International Test Protocol for validation of blood pressure measuring devices in adults" of the European Society of Hypertension has been carried out.

The BP-200 plus has satisfactory passed all tests.

Conclusion

The results of the above mentioned tests demonstrates that the BP-200 plus is equivalent in safety and efficiancy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2007

Schiller AG
c/o Reto Kuettel
Altgasse 68
Baar, ZG
SWITZERLAND 6341

Re: K063814
Trade Name: BP 200 Plus
Regulation Numbers: 21 CFR 870.1130 and 21 CFR 870.2700
Regulation Names: Noninvasive Blood Pressure Measurement System, and Oximeter
Regulatory Class: Class II
Product Codes: DXN, DQA
Dated: December 14, 2006
Received: December 22, 2006

Dear Mr. Kuettel:

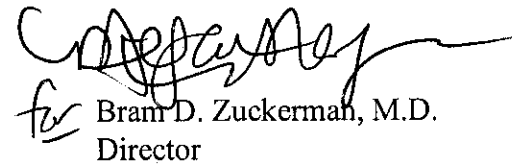
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063814

Device Name: BP-200 plus

Indications For Use:

The BP-200 plus is intended to be used as an adjunct to exercise stress testing devices. It is intended to measure and display diastolic and systolic blood pressure, heart rate, percentage of oxygen saturation in arterial blood (SpO2) and pulse rate in adult or adolescent patients during stress tests. The measurement cuff of the BP-200 plus in intended to be placed on the upper right arm of the patient. The BP-200 plus can be used for patients of both sexes and all races. The BP-200 plus should not be used with neonates.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063814